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AWARD NUMBER: W81XWH-08-1-0057

TITLE: The Development of Prostate Palpation Skills Through Simulation Training May Impact Early Detection of Prostate Abnormalities and Early Management

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REPORT DATE: May 2009

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE
1 May 2009

2. REPORT TYPE
Annual

3. DATES COVERED
1 May 2008 – 30 Apr 2009

4. TITLE AND SUBTITLE

The Development of Prostate Palpation Skills Through Simulation Training May Impact Early Detection of Prostate Abnormalities and Early Management

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-08-1-0057

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

University of Virginia
Charlottesville, VA 22904

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
This is our first annual report. Our team has made good progress on our three year grant toward achieving aims. We have 5 journal papers either submitted or with physical artifacts near completion. We have recruited a group of students and have established collaborations with other researchers, in particular to gain access to tissue specimens. We have successfully built and validated a materials characterization procedure, a series of algorithms for detecting finger palpation patterns, began formalizing contextual feedback and began formulating an algorithm to allow computerized adaptive testing principles to be applied to reduce simulation exam duration. We will continue to work toward aim completion over the next two years of the grant.

15. SUBJECT TERMS
No subject terms provided.

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
					USAMRMC
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER *(include area code)*
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Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

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Introduction

Our team is composed of the PI, Gregory J. Gerling, PhD, School of Engineering and two co-Is Reba Moyer Childress, MSN, FNP, School of Nursing and Marcus L. Martin, MD, School of Medicine. We have been working with two graduate students (Ninghuan Wang and Leigh Baumgart) and two undergraduate students (Angela Lee and William Carson). We work also in conjunction with O. John Semmes, PhD, Eastern Virginia Medical School (EVMS) and Beatriz Lopes, MD, University of Virginia, Autopsy Services.

The following series of aims and tasks had been laid out in the grant application according to the timeline. We discuss in the body of the document our progress toward achieving those aims. Those aims and tasks that are underlined and bolded have begun, some ahead of schedule.

Aim 1. Determine distinct skill levels for discernment of palpable characteristics.

- **Task 1.a)** Characterize anatomical attributes and pathological stages of disease.
- **Task 1.b)** Determine the range of disease states that are palpable and simulate.
- Task 1.c) Determine appropriate training scenarios to cover skill levels of various individuals.

Aim 2. Determine how contextual factors in the exam influence diagnosis decision-making.

- **Task 2.a)** Setup contextual scenarios.
- Task 2.b) Setup human-like aspects of standardized patient in simulated training environment.

Aim 3. Determine methods to customize performance assessment and training intervention.

- **Task 3.a)** Setup assessment based first on "up-down" or computerized adaptive testing (CAT) strategies.
- Task 3.b) Determine training interventions and levels of feedback.

Aim 4. Determine if applied finger techniques correlate with level of performance.

- **Task 4.a)** Correlate general aspects of technique with measures of assessment.
- **Task 4.b)** Correlate technique patterns of experts and novices with measures of performance assessment.

(Task 5) Plan for interaction with EVMS and U.Va. Biomaterials

Timeline for Completion of Major Tasks

Year	2008								2009												2010												2011				
Task	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M
1.a																																					
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3.b																																					
4.a																																					
4.b																																					
5	Begins before May 2008, immediately upon notice of award funding																																				

Body

<u>Aim 1</u> seeks to determine distinct skill levels for discernment of palpable characteristics.

<u>Task 1.a</u> is to characterize anatomical attributes and pathological stages of disease. Undergraduate student William Carson is working in this area. Over the past year we have built the indenter and begun validating it with silicone-elastomer samples and with normal autopsied prostates at U.Va and cancerous prostates at EVMS. I attach below the draft abstract we are preparing for the journal article listed in *Key Research Accomplishments* below. We are also collecting data on a second paper where the number of prostates will near 30.

Background: Characterization of the mechanical properties of many biological tissues and organs is often divorced from the clinic, where we could more readily attain measurement in normal or in diseased states. Such measurements could provide insight into the potential relationships of material stiffness with disease state, in addition to informing medical simulator design. *Methods:* We develop here a spherical indentation technique for the clinical setting that can determine *ex vivo* the elastic modulus of soft biological tissue; specifically prostate tissue. In addition to parameter validation (velocity, depth and diameter of sphere), we compared four calculations of elastic modulus across synthetic and biological specimens. *Findings:* Differences between prostate tissue with stones (about 400 kPa) and normal tissue (20-70 kPa) were readily detectable. Also among modulus estimation techniques, the Oliver-Pharr method relating stiffness and contact area to reduced modulus was the best predictor with the lowest standard deviation between repeated runs also aligned well with the results of tensile tests with synthetic silicone-elastomers. *Interpretation:* The spherical indenter and elastic modulus estimation developed here appears to be accurate enough to determine differences between diseased and normal tissue. The technique does not damage tissue and can be operated in the clinic by a novice in a 15 minute timeframe.

Figure 1 shows the indenter and user interface, designed for use by a clinician.

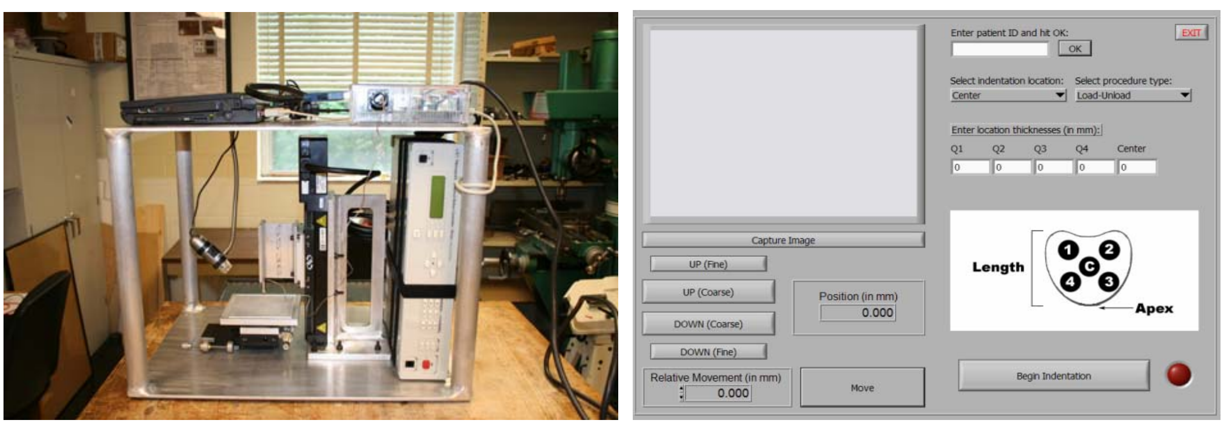


***Figure 1*: *(left)* Spherical indenter hardware and electronics housed upon the aluminum superstructure, (right) Graphical user interface of control system for indenter.**

Across both synthetic silicone-elastomer and biological materials, we have now validated spherical indentation parameters, such as indentation velocity and sphere diameter and have tested various means of calculating elastic modulus (compressive strain, indentation strain, Hertzian contact, and stiffness-to-area) and energy dissipation. We have found that the stiffness-to-area method of calculating elastic modulus aligns best both with the results from a set of tensile tests with the same synthetic materials (less than 1% difference in calculated modulus). Briefly, this method (Oliver-Pharr) directly relates stiffness and contact area to reduced elastic modulus,

$$E_r = \frac{S\sqrt{\pi}}{2\sqrt{A}}$$

where *S* is stiffness given by the rate of change in load with respect to indentation depth at the instant of unloading during a load-unload cycle (see circle in Fig. 2), *A* is the surface area of a hemisphere, and E_r is reduced elastic modulus. The value 0.75*E_r is approximately the modulus of the soft sample.

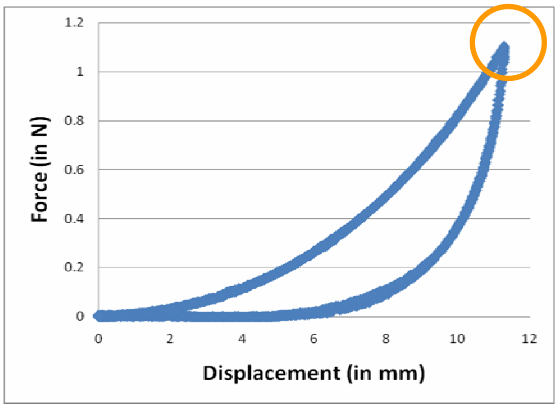


Figure 2: Example force-displacment curve for the spherical indentation of a single autopsy prostate

Preliminary elastic modulus data are presented for five autopsied prostates, where we were able to differentiate prostate stones from the surrounding normal tissue (Fig. 3, Prostate 2, Q4 v. Q2) and found consistent readings in modulus for prostates as BPH and normal (Table 1, Prostates 1, 3-5).

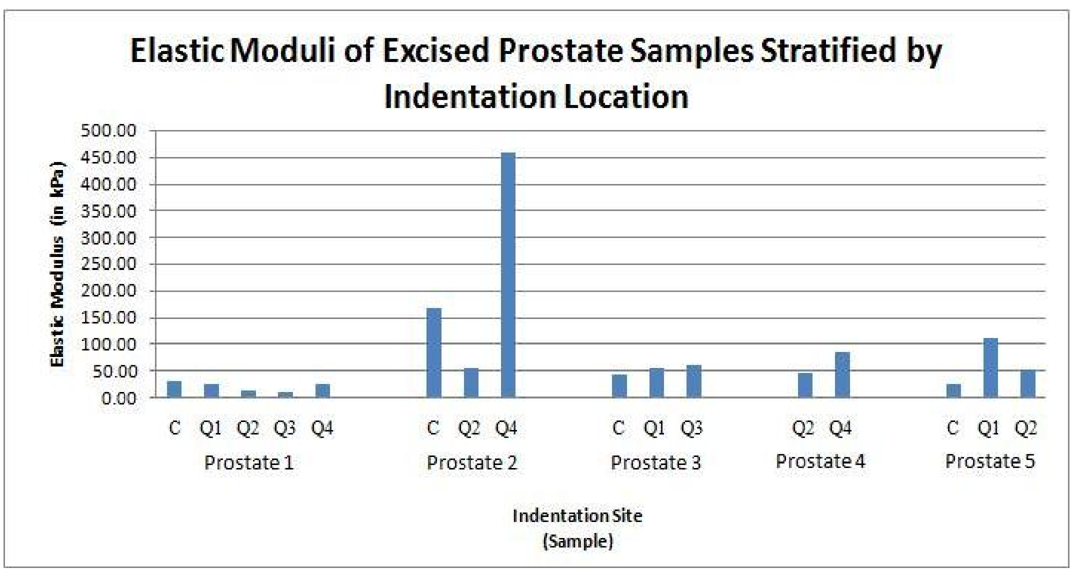


Figure 3: Elastic moduli for five autospy prostates using the stiffness-to-area method.

Table 1: Pathological diagnosis of the same five autopsy prostates.

Sample	Consistency	Diagnosis
1	Nodular	BPH
2	Nodular	Prostate stones, normal
3	Nodular	BPH
4	Nodular	BPH
5	Unremarkable	Normal

We are currently working to increase the number of samples we have measured. We are measuring tissue now at EVMS and expect to acquire 2 measurements per week over the next few months. We have also setup the logistics to collect tissue properties at U.Va. once the indenter returns from EVMS, mid-June 2009.

<u>Task 1.b</u> is to determine the range of disease states that are palpable and simulate. Graduate student Leigh Baumgart is working in this area. I include the draft abstract we are preparing for the journal article listed in *Key Research Accomplishments* below. We are also collecting data on a second paper which will be submitted to a psychophysics venue and which extends on this first paper with indenter of Task 1.a. We will test the simulated silicone-elastomer prostates to determine what the indenter detects compared to the human subject.

Background: Although the digital rectal exam (DRE) is a common method of screening for prostate cancer, the limits of ability to perform this hands-on exam are unknown. Perceptible limits are some unresolved function of the size, depth and hardness of abnormalities within a given prostate stiffness. *Methods:* To better understand the perceptible limits of the DRE, we conducted a psychophysical study with 18 participants using a custom-built apparatus to simulate prostate tissue and abnormalities in various configurations. Utilizing a modified version of the psychophysical method of constant stimuli, we uncovered thresholds of absolute detection and variance in ability between examiners. *Results:* Within silicone-elastomers that mimic normal prostate tissue, only abnormalities of diameter greater than 4 mm (20 mm^3 in volume) were consistently detectable (above 75% of the time) at the shallowest depth (5 mm). In contrast to this substrate stiffness which is 21 kPa, abnormalities located in simulated tissue of greater stiffness (82 kPa) must be twice that volume. *Conclusions:* This study finds that size and depth of abnormalities most influence detectability, while the relative hardness between abnormalities and tissue affects detectability for some size-depth combinations. The work is useful for informing the development of training and allowing clinicians to set performance expectations.

Figures 4 and 5 show the high-level results of the psychophysical experiment. As can be observed, the abnormalities positioned in shallower depths are more readily detectable, as are abnormalities of larger size. A comparison of the figures also indicates that substrate stiffness also plays a role.

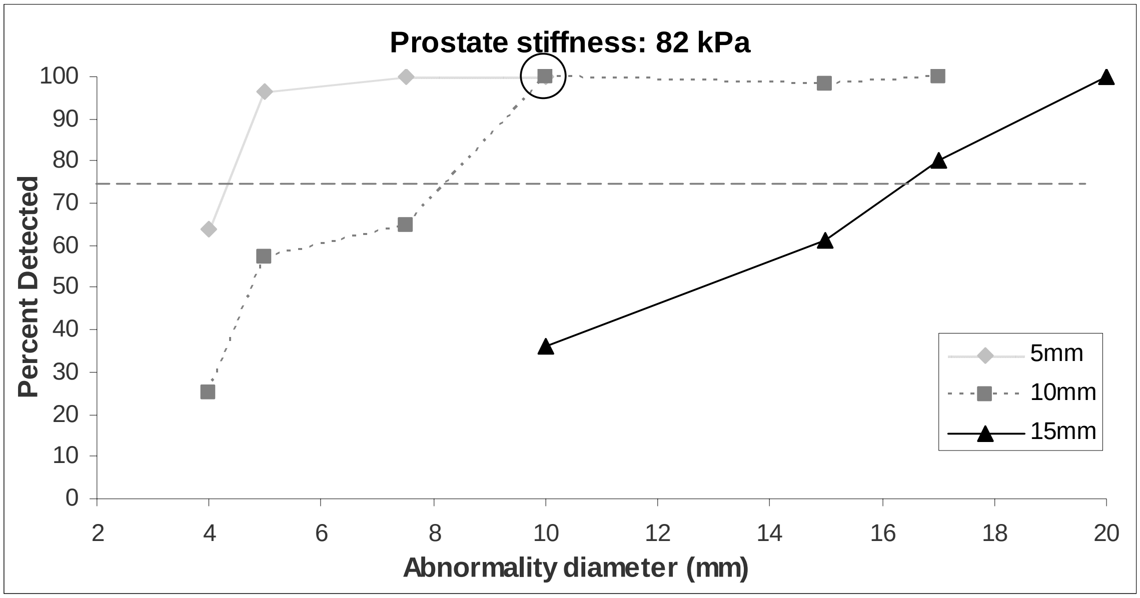


Figure 4. Psychophysical functions for the detectability of abnormalities of various diameters and depths for prostate stiffness of 82 kPa. Dotted line denotes 75% correct threshold.

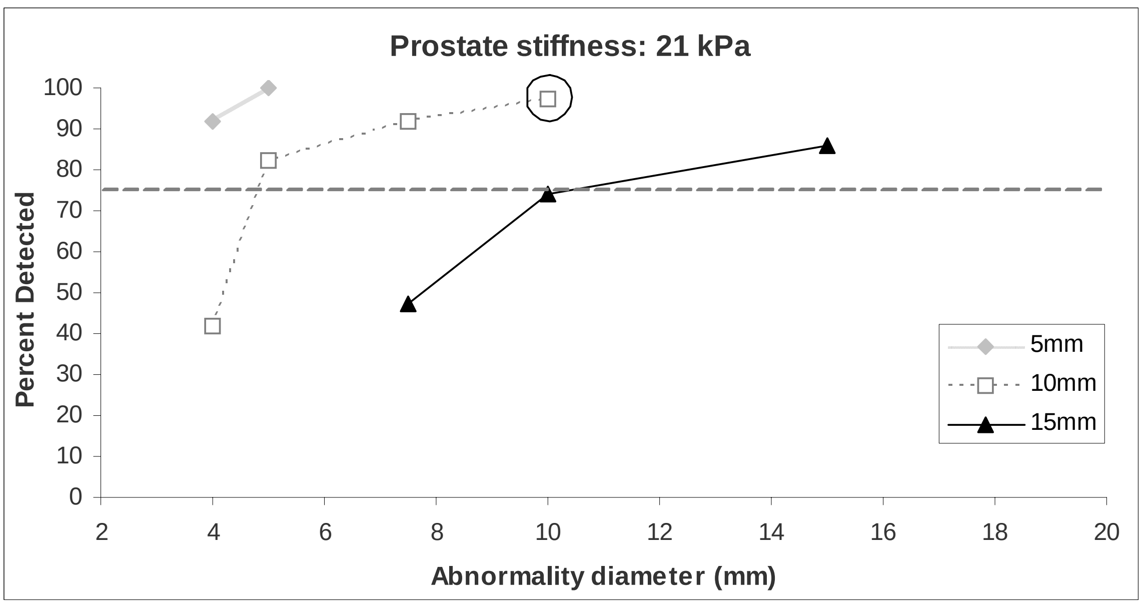


Figure 5. Psychophysical functions for the detectability of abnormalities of various diameters and depths for prostate stiffness of 21 kPa (more pliant).

Task 1.c is scheduled to begin this coming summer. We will be integrating a nursing student who will help us develop the scenarios.

Aim 2 seeks to determine how contextual factors in the exam influence diagnosis decision-making.

Task 2.a is to setup contextual scenarios. We have begun to do this by the preliminary development of user interface concepts. Figure 6 shows the opening screen.

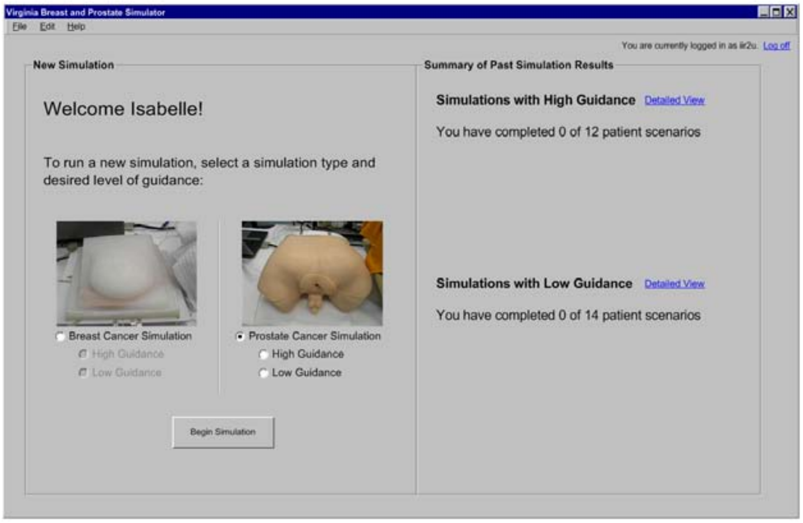


Figure 6: The screen when a user logs in for the first time.

In Figure 7, the user selects a patient scenario by clicking on the picture of the appropriate patient. Here, he or she may choose to perform the patient scenario or may view additional details about the patient. Another version of the interface abstracts the images of the prostates, if it is the case that the learner is selecting the scenarios, so not to provide the answers before the test begins.

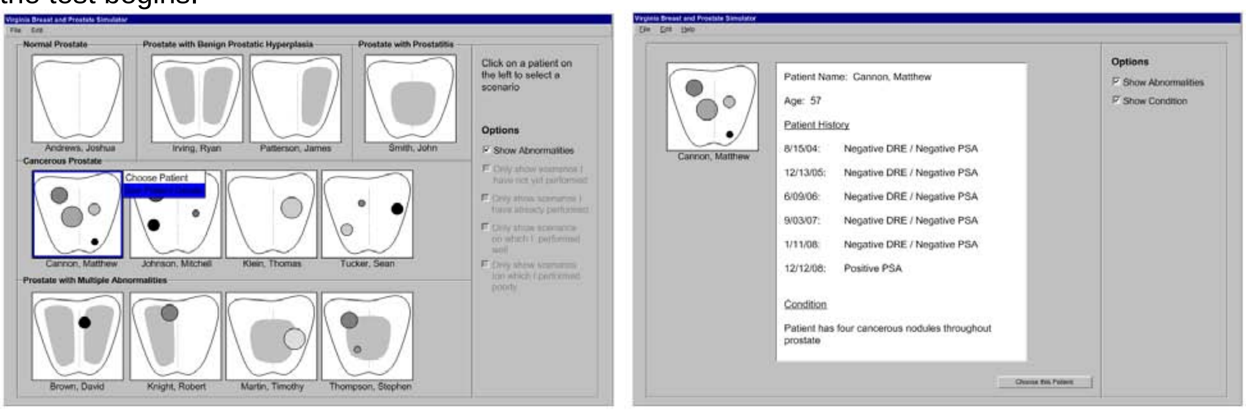


Figure 7. (left) Scenario selection with abnormalities shown and a specific patient selected and (right) Detailed view for patient Matthew Cannon

Once the simulated tumors are filled with water, it is time for the user to begin the exam. While palpating, the user will see the screen depicted in Figure 8. The user knows where he or she is palpating at a given time by looking at the red shading on the larger picture. The interface also displays a smaller picture that depicts all locations on the prostate that has already been palpated. The user knows how many abnormalities are being simulated by how many circles appear on the picture of the larger prostate and knows which abnormalities have been palpated because the circle becomes darker as the water pressure in the line spikes.

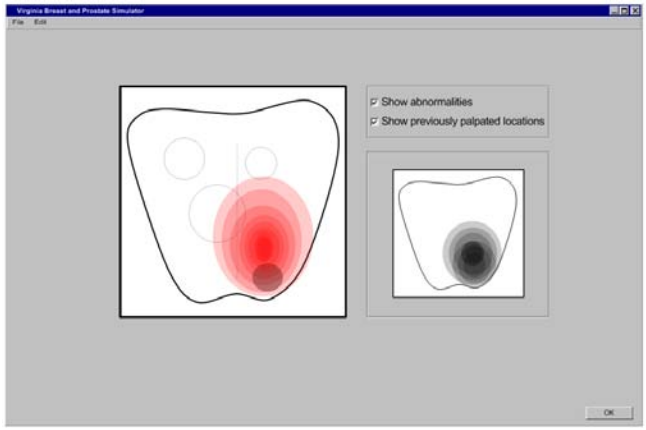


Figure 8: Screenshot of the feedback displayed to a user while he or she is palpating.

Three types of post-performance feedback are provided to a user after the simulation. The first, time elapsed, is depicted in Figure 9a, force exerted is depicted in Figure 9b, and percentage of the prostate palpated is shown in Figure 9c. Each of these prominently displays the criterion for a successful run and a green check mark or a red X to indicate whether the criteria were met.

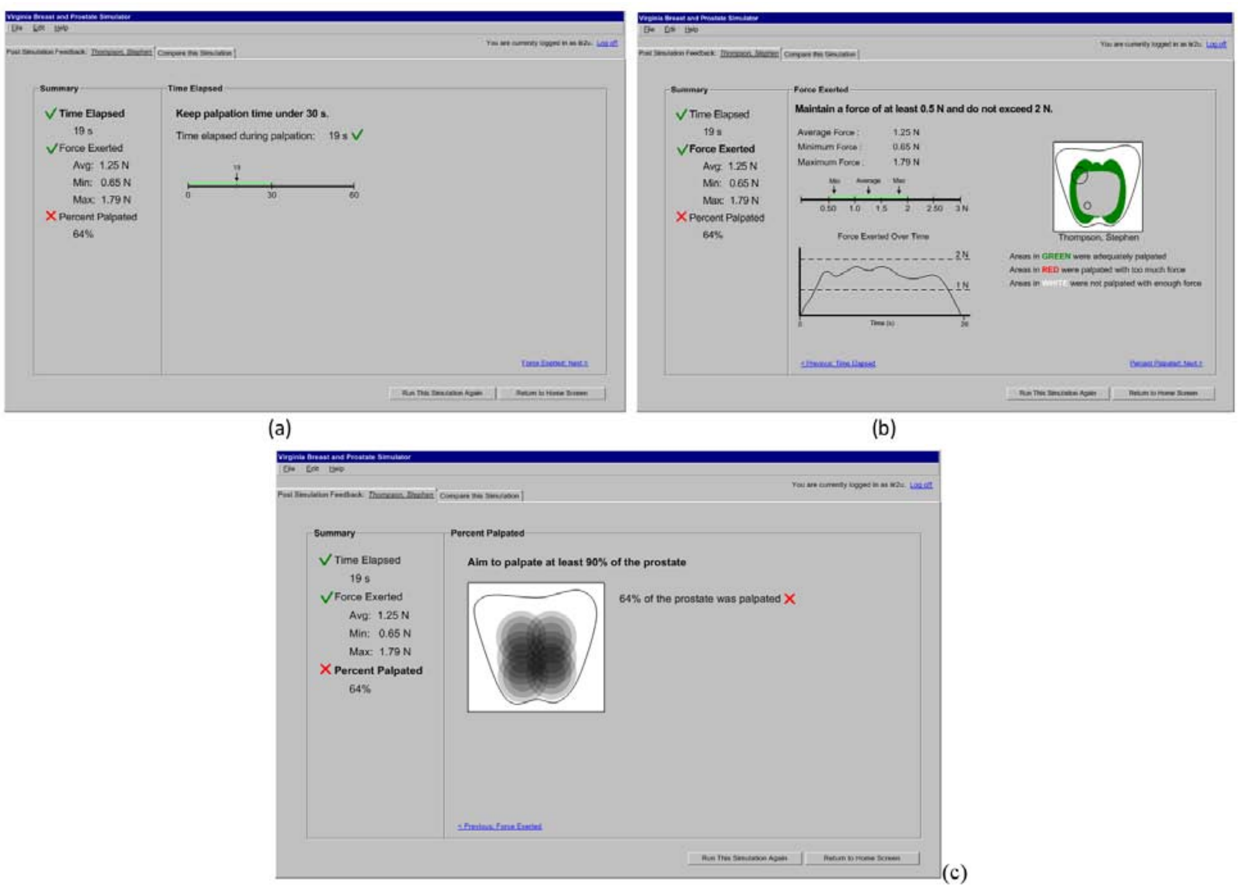


Figure 9: Screenshots of the post-performance feedback provided to the user

These designs are preliminary and have not been formally integrated with the simulator code. This will be done over the next year after we have determined that these are useful demonstrations of feedback and make sense to the user in a usability context.

Task 2.b will begin next year. It is the only task that is behind schedule, but this is not seen as a critical issue, compared to the other tasks. It seeks to setup human-like aspects of standardized patient in simulated training environment.

<u>Aim 3.</u> seeks to determine methods to customize performance assessment and training intervention.

<u>Task 3.a</u> is to setup assessment based first on "up-down" or computerized adaptive testing (CAT) strategies. Undergraduate student Angela Lee is working in this area. The following is a synopsis of the direction taken so far in this task.

Due to the hundreds of possible prostate scenarios created by VPES, it is impossible to efficiently assess the palpation skill levels of trainees within a reasonable time frame. This work seeks to integrate Computerized Adaptive Testing (CAT) with VPES for more efficient and immediate assessment of palpation performance. By integrating CAT with VPES, we can provide equally proficient ability estimates with fewer items, thereby reducing testing duration. The main components in our CAT exam are to develop an item bank of prostate scenarios, implement the item response theory (IRT) and an item selection procedure, and determine the stopping criteria and scoring method. Using the three parameter logistic model, the developed computer algorithm selectively chooses subsequent prostate scenarios based on responses to previous prostate scenarios. The three parameters that characterize each prostate scenario are difficulty, item discrimination, and the guessing parameters. An initial experiment will be conducted to create an item bank of various prostate scenarios, and determine the values for the three parameters. Therefore, experiment 1 will be conducted with 20-30 participants that represent low, medium, and high performers based on experience (novices, nurse practitioners and residents, and experts, respectively). The resulting item bank will be implemented with the developed CAT for experiment 2 where the same participants will return 2 months later. The first hypothesis is that low performers will have lower palpation abilities than high performers. The second hypothesis is that the assessment made in experiment 2 is equal to that of experiment 1 but with a reduced time length. While this work is the fundamental beginning to configure the parameters of the CAT model, future work will test the ability of the CAT algorithms to assess trainee skill in medical simulator tasks.

The four main components in the CAT as we have implemented are delineated in Figure 10.

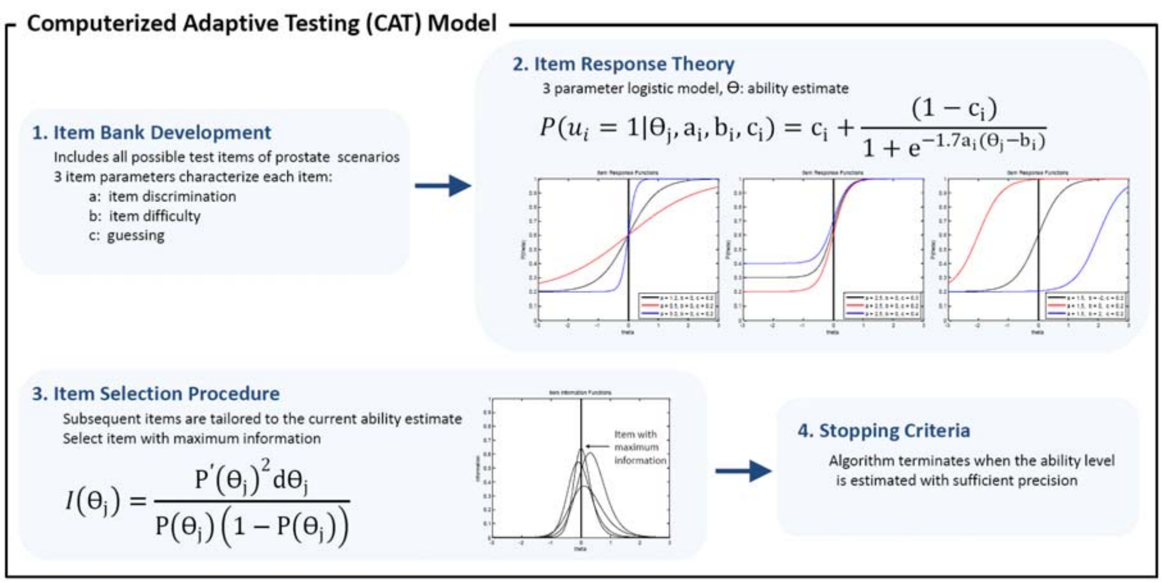


Figure 10: Four main steps in the CAT implementation (abstracted) as applied to VPES

To enable the CAT style of test administration, we had to build a new prostate torso apparatus that could hold 10 instrumented prostates, instead of the previous 3. Figure 11 shows the scenarios that each of the new 10 simulated prostates can offer.

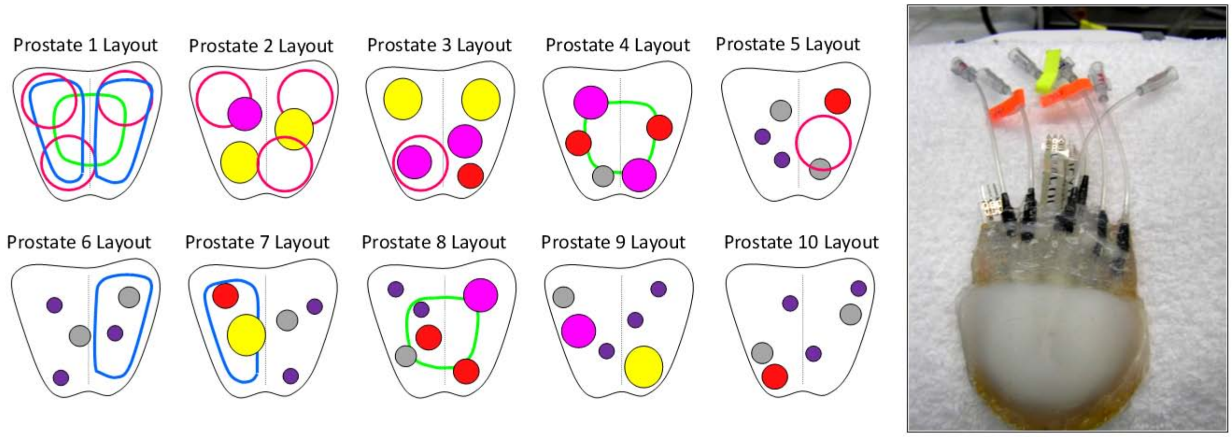


Figure 11: VPES Version 2.0 instrumented prostates and scenario generation, modified to accommodate the requirements of at least 200 scenarios for a CAT implementation.

The image sequence in Figure 12 shows an example iteration of CAT implemented with the VPES simulator. The participant is asked three questions. The first question is of medium difficulty and the participant answers correctly. Therefore, the next question is automatically selected to be of greater difficulty. This one is answered incorrectly which leads to an easy question. This process will help us to identify participant ability in fewer questions by reaching a stable ability state in few questions. At present, we have begun to implement this with computer code and plan to run experiments over the next year.

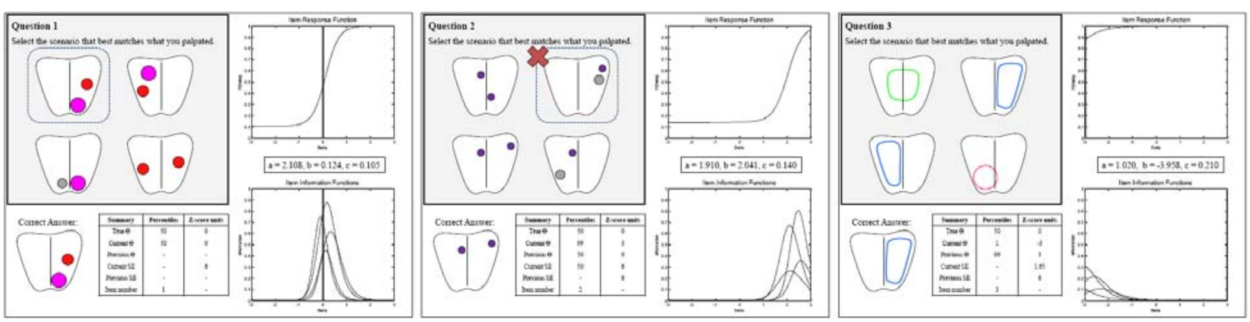


Figure 12: Example sequence of three questions administered to participants in a sequence

Task 3.b is not set to begin until next year. It seeks to determine training interventions and levels of feedback.

Aim 4. seeks to determine if applied finger techniques correlate with level of performance.

Tasks 4.a and 4.b are to correlate general aspects of technique with measures of performance assessment and correlate technique patterns of experts and novices with measures of performance assessment. Graduate student Ninghuan "Miki" Wang is working in this area. I will attach the draft abstract we have submitted for the journal article listed in *Key Research Accomplishments* below.

Objective: This work seeks to quantify finger palpation techniques in the prostate clinical exam, determine their relationship with performance in detecting abnormalities, and differentiate the tendencies of nurse practitioner students and resident physicians. *Background:* Current screening for prostate cancer combines the prostate specific antigen (PSA) blood test with the digital rectal examination (DRE). Problems with the DRE are that performance in detecting tumors greatly varies and agreement between-examiners is low. The utilization of particular palpation techniques may be one way to improve clinician ability. *Method:* Once qualitative techniques were algorithmically defined for the DRE, i.e., global finger pattern, local finger pattern, and average intentional finger pressure, a custom-built simulator recorded finger movements in a pilot experiment with two groups: 18 nurse practitioner students and 16 resident physicians. *Results:* Technique utilization varied both between participants on the same simulated abnormality and within each participant across the six abnormalities. However, some elements of technique clearly impacted performance. For example, those who utilized the local finger pattern of vibration were significantly better at detecting abnormalities. Also, the V global finger pattern led to greater success, but finger pressure played a less important role. Interestingly, while resident physicians were clearly superior in detecting abnormalities, their techniques differed only subtly from nurse practitioner students. *Conclusion:* While the pilot results would be reinforced by a larger participant set, the quantified techniques, based on past qualitative instruction, appear to account for examination ability at some level but not entirely for differences between groups.

As indicated in Figures 13 – 15, we have now setup algorithms to quantify finger palpation patterns and examined palpation patterns of medical resident physicians and nurse practitioner students who identified that palpation via a particular method was associated with improved detection rates. In depth analysis of the palpation technique ascertained that global finger movement (GFP), local finger movement (LFP), and average intentional finger pressure (AIFP) were key components of this palpation technique (Fig. 13, Analysis Tool). In short, GFP is defined as the systematic movement of one's finger over the entire prostate (U, V, L, and Line patterns) while LFP is defined as palpation by finger movement within a single quadrant of the instrumented prostate or near a single abnormality. Three patterns are defined as tapping, vibration and sliding. Finally, we calculate AIFP as that applied over the duration of the exam in the vicinity of filled balloons.

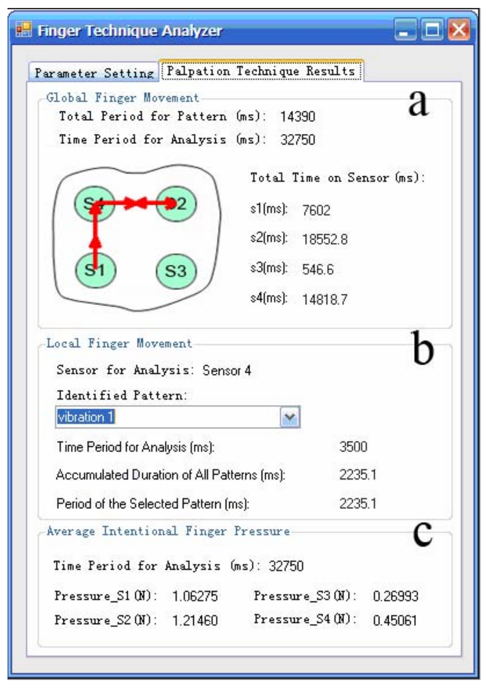
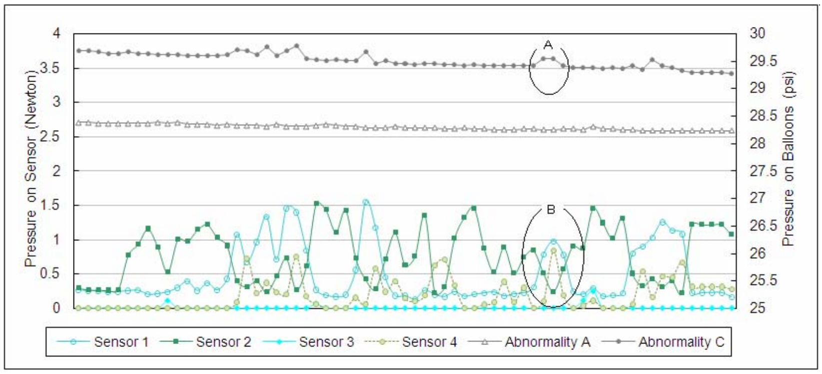


Figure 13: Palpation Technique Analyzer and Analysis Results, including a) Global Finger Pattern, b) Local Finger Pattern and c) Average Intentional Finger Pressure.

The continuous nature of the recording from force and balloon sensors (Fig. 14, left) allows for the quantification of these patterns.



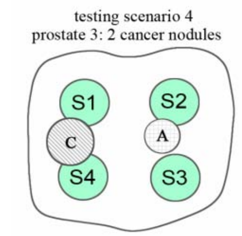


Figure 14: Example Plot of Force Sensor and Balloon Sensor Data for an Example Testing Scenario

With "local" finger pattern as an example, we show more formally the mathematical definition of the three local patterns (tapping, vibration and sliding), Fig. 15.

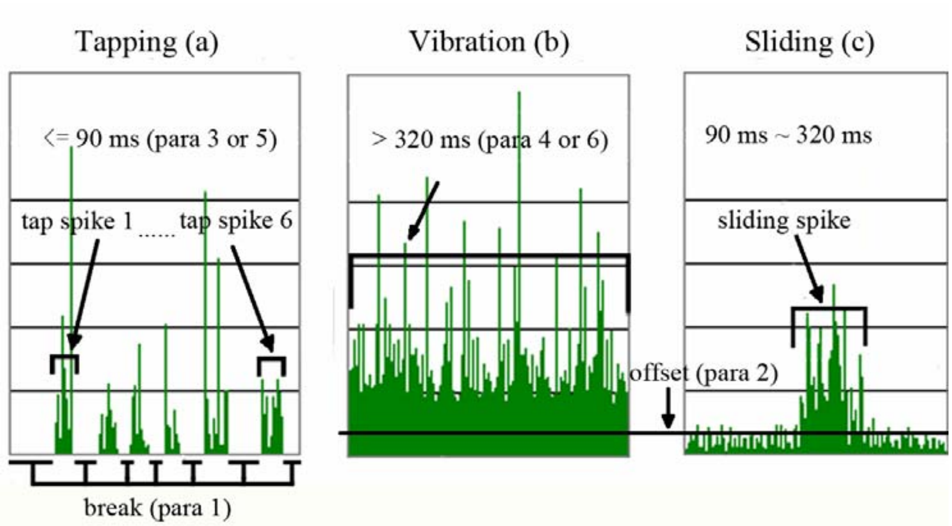


Figure 15: Three local finger palpation patterns of tapping, vibration and sliding.

The local tapping pattern is defined formally for the i^{th} sensor L^{i}_{tap} in equation below, where the period between time j and k is a break with no spikes (para 1).

$$L^{i}_{tap} = \left(\left(\sum_{t=j}^{k} t_{S\_Spike^{i}_{t}} \leq 90\right) \;\&\; \left(\left(t_{S\_Spike^{i}_{j}} - t_{S\_Spike^{i}_{k}}\right) < 48\right)\right), \;\; j>k$$

Visible in the data of Figure 8b, the vibration pattern is defined formally for the i^{th} sensor in equation below as an examiner maintaining finger pressure above a certain value (para 2) on the prostate over a continuous time span of at least 320-msec.

$$L^i_{vibr} = ((\sum_{t=j}^{k} t_{S\_Spike^i_t} \geq 320) \; \& \; (S\_Spike^i_t > offset))$$

The sliding pattern comes in contrast to the tapping and vibration patterns where the examiner appears to transition from the global finger pattern to an intentional focus upon the local detection of a balloon. Visible in Figure 8c, the sliding pattern is defined formally for the ith sensor in equation 7 as an examiner maintaining pressure above a certain value (para 2) continuously for 90 to 320-msec.

$$L^i_{sl} = ((90 < \sum_{t=j}^{k} t_{S\_Spike^i_t} < 320) \; \& \; (S\_Spike^i_t > offset))$$

Our preliminary findings in tests with non-urological resident physicians and nurse practitioner students are that some elements of technique clearly impact performance in detecting abnormalities. For example, those who utilize the local finger pattern of vibration are significantly better at detecting abnormalities. Also, using the V global finger pattern lead to greater success, but finger pressure plays a less important role.

From here we are attempting to setup a study with urologist attendings at U.Va. and have been working with a new researcher in the U.Va Department of Urology to determine the logistics. Basically we plan a single blinded study design. The palpation technique utilized by each of the 11 urologists in a 20 min VPES session will be digitally recorded for subsequent analysis. The urologists will believe that the sole purpose for the study is to replicate authenticity with the simulator when a secondary endpoint will be palpation technique. Multiple reconfigurations and stages of prostate disease will be simulated increasing in difficulty, based on our prior findings in laymen. The global finger movement, local finger movement, and average intentional finger pressure will be quantified and correlated with diagnostic accuracy.

Task 5 is to setup the interaction with EVMS and U.Va. Biomaterials. Task 5 has been completed. We now have IRB agreements in place at the University of Virginia and Eastern Virginia Medical School. These have also been approved by the IRB of the Department of Defense.

Key Research Accomplishments

We list several journal and conference publications, either already presented, currently under review, or to be submitted in the next 2-3 months.

Peer-reviewed publications in progress or submitted

- Wang, N, Gerling GJ, Moyer Childress, R and Martin, ML, Quantifying Palpation Techniques in Relation to Performance in a Clinical Prostate Exam (under review with the Journal of the Human Factors and Ergonomics Society)
- Carson, WC and Gerling GJ, A spherical indentation technique for clinical characterization of *ex vivo* prostate tissue and validation with silicone-elastomers (in preparation for May/June submission to The Journal of Urology)
- Baumgart, LA, Gerling, GJ, and Bass, EJ, Characterizing the range of prostate abnormalities palpable by digital rectal examination (in preparation for May/June submission to Cancer Detection and Prevention)
- Gerling GJ, Moyer Childress, R, and Martin, ML, Learner-centered Simulation to Teach Digital Rectal Examination of the Prostate Gland: Combining Self-directed and Active Learning with Instructor Assessment (in preparation)
- Wang, N, Gerling GJ, Moyer Childress, R and Martin, ML, Clinical Interpretation of the Quantification of Finger Patterns Employed in the Digital Rectal Examination (in preparation for the Journal of Simulation in Healthcare)

Conference papers and presentations (peer-reviewed)

- Wang, M., Gerling, G.J., Moyer Childress, R., and Martin M.L. “Characterizing Finger Palpation in the Detection of Prostate Cancers and Abnormalities” (Proceedings of the Human Factors and Ergonomics Society 52nd Annual Meeting, 2008, New York City, NY, pp. 813-817)
- Moyer Childress, R., Gerling, GJ, and Martin ML, “Collaborative Simulation Research to Improve Student Education and Patient Outcomes,” (Poster to be presented at the 8th International Nursing Simulation/Learning Resource Centers Conference on June 10 - 13, 2009 in St. Louis, Missouri.

Student conferences (not peer-reviewed)

- Carson, WC, Calculating the Elastic Modulus of Prostate Tissue in a Clinical Setting Using Spherical Indentation (IEEE SIEDS Conference, April 20, 2009, Charlottesville, VA)
- Lee, A., Applying Computerized Adaptive Testing to the Virginia Prostate Examination Simulator (IEEE SIEDS Conference, April 20, 2009, Charlottesville, VA)
- Wang, N., Characterizing finger palpation in the detection of prostate cancers and abnormalities (Virginia Tech HFES Student Conference, October 15, 2009, Blacksburg, VA)
- Carson, WC., Determining the material properties of prostate tissue to improve simulator realism (Virginia Tech HFES Student Conference, October 15, 2009, Blacksburg, VA)
- Lee, A., Applying computerized adaptive testing to the Virginia Prostate Examination Simulator for the improved assessment of skill (Virginia Tech HFES Student Conference, October 15, 2009, Blacksburg, VA)

Students graduating

- Ninghuan Wang (to graduate with Master of Science, May 2009)
- Bill Carson (to graduate with Bachelor of Science, May 2009)

- Angela Lee (to graduate with Bachelor of Science, May 2009)

In terms of Public Service and Outreach, we have also presented to the public in several venues both in the popular press and with booths at the one-to-one level.

Coverage in Popular Press

- NBC 29 Interview: “Simulator Helps UVA Doctors Detect Cancer” (January 26th, 2009) Newscast available for viewing at: http://www.nbc29.com/global/story.asp?s=9730404
- Cavalier Daily Newspaper Article: “New Simulator Provides Unique Practice” (January 27th, 2009) Story available for reading at: http://www.cavalierdaily.com/news/2009/jan/27/new-simulator-provides-unique-practice/

Presented at a booth at the Charlottesville Community Health Fair, in conjunction with the 19th annual African-American Cultural Arts Festival in Booker T. Washington Park, Saturday, July 26, 2008, Attended and demonstrated the Virginia Prostate Examination Simulator, our research and posters, along with group informing the public about prostate and breast cancer.

Reportable Outcomes

Several papers are now under peer review or to be submitted. All aims, with the exception of Task 2.b) are on or ahead of schedule.

Conclusions

Our team has made good progress on our three year grant toward achieving aims. We have 5 journal papers either submitted or with physical artifacts near completion. We have recruited a group of students and have established collaborations with other researchers, in particular to gain access to tissue specimens. We have successfully built and validated a materials characterization procedure, a series of algorithms for detecting finger palpation patterns, began formalizing contextual feedback and began formulating an algorithm to allow computerized adaptive testing principles to be applied to reduce simulation exam duration. We will continue to work toward aim completion over the next two years of the grant.

References

None applicable.

Appendices

None applicable.